REMARKS

Claims 1-28 and 32-37 are pending in the current application. Claims 29-31 have been cancelled. Claims 1 and 25 have been amended to require Py to represent pyridin-4-yl substituted with methyl or ethyl at the 6 position. Support for the amendment in claim 1 may be found from page 4, line 10 to page 5, line 18 and page 6, lines 25-26. Support for the amendment in claim 25 may be found from page 16, line 4 to page 17, line 11 and page 18, lines 3-5. Claims 1, 2, 5, 8-11, 14, 17-22 and 25-28 have been amended to provisionally cancel the non-elected inventions. Claims 3, 4, 6, 7, 12, 13, 15, 16, 23, 24, 32-37 are provisionally withdrawn.

The examiner issued an eleven-way restriction, claiming that Groups I-XI are not related to a single general inventive concept required under PCT Rule 13.1 because they lack the same or corresponding special technical features. *Office Action*, 1/22/2009, p.4. The Examiner argued that the claimed compounds do not define a contribution over the art, arguing that the common core is found in U.S. Patent 6,331,541 (Ko et al.).

As a primary matter, Applicants seek clarification from the Examiner with respect to the grouping of claims and the restriction requirement. The Examiner restricted the claims to eleven groups, wherein Groups I-V relate to compounds and pharmaceutical compositions of Formula I, wherein n = 1; Groups VI-X relate to compounds and pharmaceutical compositions of Formula I, wherein n = 2; and Group XI relates to a method of treating a patient suffering from urotensin II and urotensin II receptors and associated diseases and conditions limited to the scope of one of groups I-X. *Office Action*, 1/22/09, pages 2-4. The values of n of the claims of the invention, however, are 0 or 1, and not 1 or 2. The values of m of the claims of the invention are 1 or 2. Therefore, Applicants presume that the Examiner meant to divide Groups I-V to compounds and pharmaceutical compositions of Formula I, wherein m = 1; and Groups VI-X to compounds and pharmaceutical compositions of Formula I, wherein m = 2. Applicants invite the Examiner to confirm and clarify the restriction requirement.

The Examiner argued that the common core of the claims are described in U.S. Patent Application 6,331,541 (Ko et al.) because Ko et al. discloses a 1-(3-(4-(4-methoxybenzyl)piperidine-1-yl)butyl)-3-(pyridin-4-yl)urea and a 1-(2-(4-(4-chlorobenzyl)piperidine-1-yl)ethyl)-3-(pyridin-3-yl)urea. To expedite prosecution, Applicants have amended claim 1 to require Py to represent pyridin-4-yl substituted at position 2 with C_{1-7}-

alkyl, aryl-C_{1-7}-alkyl, or (*E*)-2-aryl-ethen-1-yl and at position 6 with methyl or ethyl. Applicants also provisionally elect, with traverse, to prosecute Group III, claims 1, 2, 5, 8-11, 14, 17-22, 25-28, drawn to compounds and pharmaceutical compositions of Formula I, wherein m = 1 and X = R^1-SO_2NR^2-; R^1-$CONR^2$-; aryl-R^8-$CONR^2$-; or R^1-NR^3CONR^2.

Amended claims 1, 2, 5, 8-11, 14, 17-22, 25-28 are all linked by the compound of General Formula I wherein Py represents pyridin-4-yl substituted at position 2 with C_{1-7}-alkyl, aryl-C_{1-7}-alkyl, and at position 6 with methyl or ethyl. Therefore, the amended compound of General Formula I requires that (1) Y represents $-C(R^6)(R^7)(CH_2)-$ or $-(CH_2)C(R^6)(R^7)-$; (2) Py represents pyridin-4-yl disubstituted in positions 2 with C_{1-7}-alkyl, aryl-C_{1-7}-alkyl or (E)-2-aryl-ethen-1-yl and position 6 with methyl or ethyl; (3) Z represents hydrogen; and (4) X represents R^1-SO_2NR^2-; R^1-$CONR^2$-; aryl-R^8-$CONR^2$-; or R^1-NR^3CONR^2. The claimed inventions are novel and unobvious over Ko et al, because Ko et al., while disclosing a large class of compounds, does not specifically disclose a compound having a pyridine-4-yl ring substituted both at the 2 and 6 positions. In addition, the amended compound of General Formula I requires that the piperidine ring substituted with a nitrogen moity (e.g., R^1-SO_2NR^2-; R^1-$CONR^2$-; aryl-R^8-$CONR^2$-; or R^1-NR^3CONR^2) while the pyridine containing compounds exemplified in Ko et al. is phenyl or benzyl substituted piperidine compound. Applicants note that although the Examiner argued that Ko et al. discloses a 1-(3-(4-(4-methoxybenzyl)piperidine-1-yl)butyl)-3-(pyridin-4-yl)urea and a 1-(2-(4-(4-chlorobenzyl)piperidine-1-yl)ethyl)-3-(pyridin-3-yl)urea, the Examiner did not cite where in the application those compounds are disclosed. As Ko et al. does not specifically disclose a compound having both a 2,6-disubstituted pyridin-4-yl ring and a piperidine ring substituted with an amide or sulfonamide moiety (e.g., R^1-SO_2NR^2-; R^1-$CONR^2$-; aryl-R^8-$CONR^2$-; or R^1-NR^3CONR^2), the compound of General Formula I is novel and unobvious over Ko et al. Significantly, the compounds disclosed in Ko et al. are useful for the treatment of inflammatory diseases and allergic disorders. The Federal Circuit has held that "post-KSR, a prima facie case of obviousness for a chemical compound still, in general begins with the reasoned identification of a lead compound" *Eisai Co. v. Dr. Reddy's Lab.*, 533 F.3d 1353, 1359 (Fed. Cir. July 21, 2008). As such, it would not be obvious to one skilled in the art to identify among the hundreds of thousands plus anti-inflammatory and anti-allergic compounds disclosed in Ko et al., 2,6-disubstituted pyridin-4-yl compounds as those disclosed in the current

invention useful as urotensin II actives. In view of these remarks, Applicants respectfully request the Examiner to reconsider and withdraw the restriction requirement.

In the event that the Examiner maintains the Restriction Requirement, and reserving all rights, including the right to reinstatement or rejoinder of any claims and/or scopes in the event the restriction requirement is withdrawn or a generic claim is allowed, and/or the right to pursue any non-elected or cancelled inventions in divisional applications, Applicants **provisionally restrict, with traverse,** to Group III, claims 1, 2, 5, 8-11, 14, 17-22, 25-28, drawn to compounds and pharmaceutical compositions of Formula I, wherein m = 1 and X = R^1-SO_2NR^2-; R^1-$CONR^2$-; aryl-R^8-$CONR^2$-; or R^1-NR^3CONR^2. Applicants also elect Example 15, *N*-(1-{2-[3-(2,5-Dimethyl-pyridin-4-yl)-ureido]-ethyl}-piperidin-4-yl)-*N*-ethyl-r-methoxy-benzenesulfonamide as a species for search purposes.

As this response is filed within one month from the mailing of the restriction requirement on January 22, 2009, which response is due by February 23, 2009, it is believed no fees are required. If this is not correct, however, the Commissioner is authorized to charge any additional fees, or credit any overpayment, to Deposit Account No. 50-4255.

Respectfully submitted,

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